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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1743

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,028

Applicant(s)

MATSUMOTO, TSUKASA

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/520,624.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/520,624, filed on March 7, 2000.

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It fails to claim priority to parent application serial no. 09/520,624 under 35 USC 120.

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

4. The abstract of the disclosure is objected to because it is not in single paragraph form, and because of the inclusion of legal phraseology such as "comprises". Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: On page 1, line 9 of the specification, the phrase –now abandoned- should be inserted after the name "Matsumoto" so as to update the status of the parent application in the section of the specification entitled "Related Applications". On pages 9-10 of the specification in the section entitled "Brief Description of Drawings", there is no brief description of Figures 1a-1g, 2a-2f, 3a-3l, 4a-4d, 5a-

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5h, 6a-6d, 7a-7f, 8a-8d, 9a-9h and 10a-10h. Applicant is requested to provide a brief description for each separate figure 1a, 1b, 1c, etc. depicted in the drawings.

Appropriate correction is required.

6. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 are indefinite since they are generally narrative, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors.

Specifically, claim 1 is indefinite since it is not known what the definition of "leucocyte components" is. This can be broadly interpreted as anything located inside the cell membrane of a leucocyte (i.e. organelles, proteins, nucleic acids, etc. within the leucocytes). In claim 1, the following phrases lack antecedent basis: "the leucocyte components", "the blood liquid" and "the separated layers or parts".

On line 4 of claim 2, the phrase "selected from" should be changed to "selected from the group consisting of"—so as to use proper Markush language. On lines 4-5 of claim 2, the phrase "the supersonic of 1MHz to 50 MHz" is indefinite since it is not clear what "the supersonic" means. Does this refer to a type of sound vibration, etc.? The phrase "several seconds to several minutes (about 3 minutes)" on line 8 of claim 2 is a relative phrase which renders the claim indefinite. It is not clear what the term "several" means. In addition, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly

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set forth the metes and bounds of the patent protection desired. In the present instance, claim 2 recites the broad recitation "several minutes", and the claim also recites "about 3 minutes" which is the narrower statement of the range/limitation. See this same problem on line 15 with the phrase "at a room temperature (about 20°C)". In claim 2, the following phrases lack antecedent basis: "the supersonic", "the laser", and "the temperature range".

On line 6 of claim 3, the phrase "corresponding the leucocyte components" should be changed to "corresponding to the leucocyte components--". This same change should also be made on line 5 of claim 4. Claims 3-4 are indefinite since they are narrative and repetitive in nature.

In claim 5, the following phrases lack antecedent basis: "the cultured leucocytes" and "the specific persons".

Claim 6 is indefinite since it is unclear how the therapeutic effects of the leucocyte components are found by using blood samples from patients suffering from various diseases since no step of combining the leucocyte components with the blood samples of the patients is positively recited.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al. (submitted in the Information Disclosure Statement filed on April 8, 2002).

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In reference example 5 in columns 24-25 of Hashimoto et al (see lines 63-67 in column 24 and lines 1-10 in column 25), a method is taught for obtaining leucocyte components from human blood which comprises fracturing the cell membranes of the leucocytes by vigorously agitating the leucocytes in a vortex mixer to effect cell rupture. This step constitutes a physical means of fracturing the cell membranes of the leucocytes. As a result of the cell rupture, the nucleic acids in the leucocytes are released. The nucleic acids are then subject to electrophoresis on an agarose gel in order to separate these leucocyte components from one another.

9. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Gottlieb (submitted in the Information Disclosure Statement filed on April 8, 2002).

Gottlieb teaches of a method for obtaining leucocyte components from human blood which comprises a first step of lysing the cell membranes of the leucocytes by subjecting the leucocytes to several cycles of freeze-thawing, and a second step of separating the released leucocyte components from one another by either dialysis or a procedure which involves centrifugation followed by ultrafiltration. See examples 2 and 3 in columns 7-8 of Gottlieb (lines 65-68 in column 7 and lines 1-45 in column 8). The cycles of freeze-thawing constitute a physical means of fracturing the cell membrane of the leucocytes, and the centrifugation/ultrafiltration constitutes a means of separating and collecting the individual leucocyte components.

10. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Wissler et al.

Wissler et al teach of a method for isolating a component known as angiotropins from cultured leukocytes. In the method, leukocytes are collected and cultured under sterile conditions. During culturing, the angiotropins migrate out of the cells and into the culture

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medium. The culture is terminated by separating the cells from the culture medium by centrifugation. The culture supernatant is further centrifuged to remove suspended particles. The resultant clear supernatant is found to contain the angiotropins. See Example A, part A.1. in columns 19 and 20 of Wissler et al. In an alternative embodiment, the cultured leukocytes are first physically homogenized, which inherently causes at least some of the leukocytes to lyse. After the homogenization, the leukocytes are centrifuged to separate the angiotropins from the blood liquid resulting from the homogenization in order to collect the separated angiotropins. See Example D in column 25 of Wissler et al. Therefore, Wissler et al teach of using a physical means for fracturing the cell membrane of at least some leukocytes in a sample (i.e. homogenization) in order to release leukocyte components therein, followed by a step of separating the leukocyte components from the blood liquid by centrifugation.

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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13. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gottlieb.

For a teaching of Gottlieb, see previous paragraphs in this Office action.

Gottlieb fails to teach of the specific conditions under which the cycles of freeze-thawing take place. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to determine the optimum temperatures/conditions for freezing and thawing the leucocytes in the method of Gottlieb since temperature is a result effective variable that can be varied as desired by a person performing the method in order to achieve optimum cell lysis.

14. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wissler et al in view of Applicant's admitted prior art on page 4 of the instant application. For a teaching of Wissler et al, see previous paragraphs in this Office action.

Wissler et al fail to teach of culturing leukocytes from healthy individuals, and finding the therapeutic effects owing to the separated angiotropins. Applicant admits on page 4 of the specification that it is known in the art to administer cultured leukocytes of a healthy individual to a patient with rheumatism in order to determine the therapeutic effects of the cultured leukocytes on the rheumatism. It was found that the cultured leukocytes are excellent in treating the patient's rheumatism.

Based upon a combination of Wissler et al and Applicant's admitted prior art, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to separate angiotropins from leukocytes of healthy individuals in the method disclosed by Wissler et al and to use the angiotropins to evaluate the therapeutic effects on patients suffering from various diseases since Applicant admits that it is known in the art to use whole cultured leukocytes from healthy individuals for the same purpose. Therefore, one of ordinary skill in the

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art would expect that components isolated from cultured leukocytes would behave similarly to the whole cultured leukocytes and also be effective for therapeutically treating patients with various diseases.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 703-308-3912. The examiner can normally be reached every Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3599.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

June 1, 2003

Maureen M. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP ~~1800~~ 1700